National Environmental Laboratory **Accreditation** Conference

nelac

PROFICIENCY TESTING

Proposed Changes

May 1, 1998

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PROFICIENCY TESTING

N O T E: ***The additions and ~~deletions~~ to the approved standards being submitted by the Proficiency Testing Committee for vote are marked as in this note.***

2.0 PROFICIENCY TESTING PROGRAM: INTERIM STANDARDS

For the period beginning with adoption of these standards by the National Environmental Laboratory Accreditation Conference (NELAC) and ending December 31, 1999 ~~September 30, 1998~~, all National Environmental Laboratory Acreditation Program (NELAP)-approved primary accrediting authorities shall accept data from proficiency testing programs that meet the requirements of current Environmental Protection Agency (EPA) or state regulations and guidance. The intent of these interim standards is to continue the status quo until remaining EPA and other stakeholder issues can be addressed. This should not be construed as NELAC approval or disapproval of any particular PT provider.

~~Accrediting~~Primary accrediting authorities may rely on the current laboratory performance evaluation studies conducted by EPA. These include: the Water Supply (WS) Study, conducted twice annually; the Water Pollution (WP) study, conducted twice annually; and the Discharge Monitoring Report Quality Assurance (DMRQA), conducted once annually. Alternatively, primary accrediting authorities may rely on other sources for performance evaluation studies (such as their own state-operated programs or programs supported by commercial vendors), provided that these programs meet current EPA regulatory requirements.

2.1 INTRODUCTION, SCOPE, AND APPLICABILITY

This chapter and the associated appendices define the major participating organizations and components of the NELAC Proficiency Testing (PT) Program. In addition to complying with the requirements of this Chapter, any person, private party or government entity seeking to participate as a PT Provider in the NELAC program shall also comply with the requirements of the applicable Appendices A (PT Provider Approval Criteria), B (PT Sample Design and Acceptance Guidelines), C (Proficiency Testing Acceptance Criteria and Proficiency Testing Pass/Fail Criteria) and D (Proficiency Testing Oversight Body). The criteria set forth in this standard are considered to be default requirements, and shall be used in the absence of specific EPA program ~~criteria~~ regulations. If they conflict with any documented

EPA program ~~criteria~~ regulations, the program ~~criteria~~ regulations shall have precedence.

Proficiency Testing (PT) is defined for the purpose of this Chapter as a means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. PT is not the sole criterion for determining accreditation status. Additional essential elements of the overall NELAC accreditation process, including the ~~laboratory audit~~ on-site assessment, are discussed in other chapters of the NELAC standards. The PT program is intended to cover all types of federal and state environmental analyses. However, the body of the PT standard applies primarily to chemistry. *Appendices (yet to be developed) will describe necessary variations as applied to radiochemistry, environmental toxicology ~~biology~~, and microbiology.*

The major components of the NELAC PT Program include:

a) multiple PT Providers who shall meet stringent criteria to become Approved by a ~~the~~ Proficiency Testing Oversight Body (PTOB), as described in Section 2.3 and Appendix A;

b) specific requirements for the design of PT samples and studies, to ensure that all samples provide a consistent, fair and known challenge to laboratories seeking ~~NELAC A~~accreditation from a NELAP-approved accrediting authority, as described in Section 2.3 and Appendix B;

c) specifically defined pass/fail criteria for evaluating PT sample results, as described in Section 2.3 and Appendix C;

d) initial approval and ongoing oversight of PT Providers by a ~~the~~ Proficiency Testing Oversight Body (PTOB), Section 2.3 and Appendix D;

e) specific requirements for laboratories participating in PTOB-a~~A~~pproved PT Programs, as described in Sections 2.5, 2.6, and 2.7; and

f) oversight of all PT Program activities by the PTOB(s), as described in Section 2.2.1.

2.1.1 Purpose

The PT program incorporates several practical purposes, which include:

a) the production and supply of test samples that are procedure-sensitive; that is, the samples challenge the critical components of each analytical procedure, ranging from initial sample preparation to final data analysis;

b) the production and supply of test samples that are as similar to real-world samples as is reasonably possible. It is further expected that the PT samples will be representative of materials analyzed for environmental regulatory programs, agencies, and communities;

c) a program which is affordable by all participants;

d) the yielding of PT data that are technically defensible on the basis of the type and quality of the samples provided;

e) the preparation of samples such that the identification and quantitation of analytes in the samples poses equivalent difficulty and challenge regardless of the manner in which the samples are designed and manufactured by the PT Providers, i.e. samples prepared for analysis by a Drinking Water or Wastewater method would pose equal challenge whether prepared as whole volume or ~~concentrated~~ as a concentrate in ampules.

2.1.2 Goals

The PT program incorporates several practical goals, which include:

a) the generation of data at a quality level required by environmental and regulatory programs;

b) the generation of data that are, at a minimum, comparable in quality to that of currently certified and/or accredited laboratories; and

c) the improvement of the overall performance of laboratories over time.

2.1.3 PT Fields of Testing

The PT program is organized by PT fields of testing. Laboratories may choose to participate in one or more PT fields of testing. The following elements collectively define PT fields of testing:

a) Regulatory or environmental program, as listed in Chapter 1,

b) Matrix type (e.g. gas, aqueous liquid, nonaqueous liquid, solid), and

c) Analyte

2.2 MAJOR PT GROUPS AND THEIR RESPONSIBILITIES

The PT program structure incorporates five major groups with separate and distinct roles and responsibilities. The groups are NELAC, the Proficiency Testing Oversight Body (PTOB), the PT Providers, the testing laboratories, and the primary Accrediting Authorities (AA). The lines of interaction among these groups are shown in Figure 2-1.

2.2.1 NELAC and NELAP

~~NELAP is the Standards Setting Authority (SSA) which is responsible for administering the~~ NELAC is the Standards Setting Authority (SSA) which is responsible for administering the NELAP PT program. EPA and the states established NELAC to develop the written standards by which the PT program will operate and to keep these standards current relative to the needs of regulatory and environmental laboratory programs. The NELAC standing Proficiency Testing Committee determines PT fields of

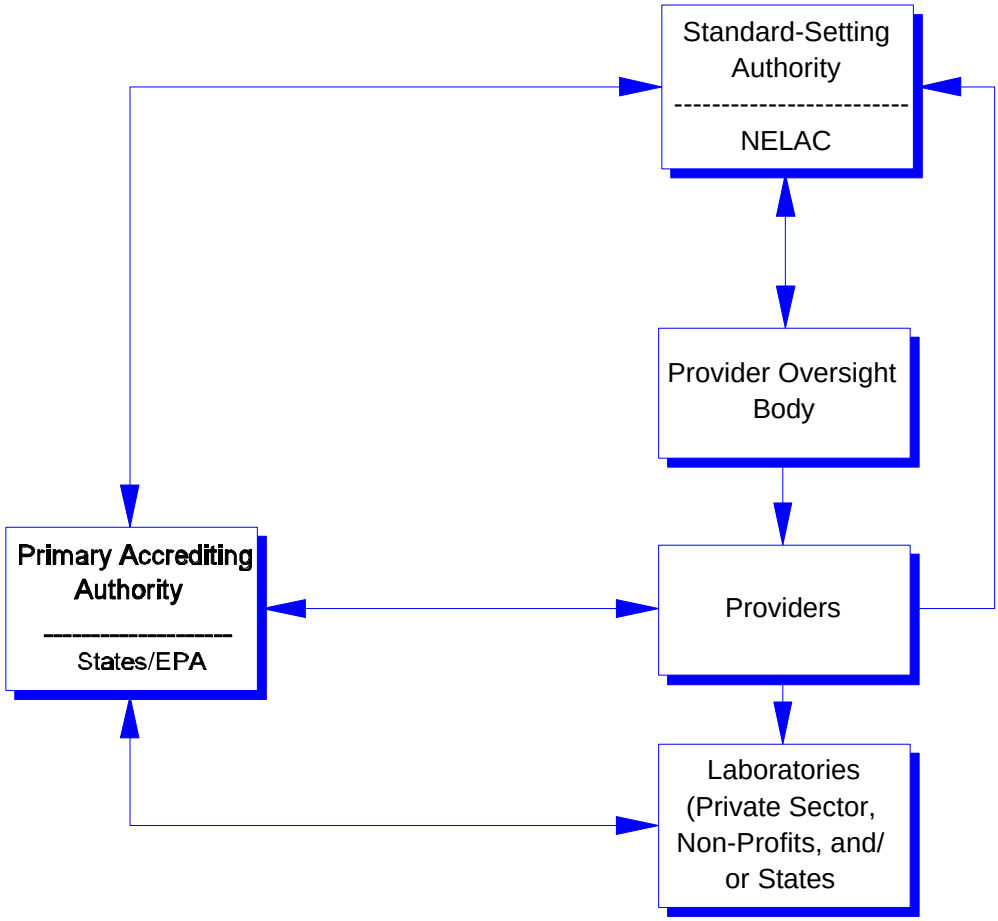

Figure 2-1. NELAP Proficiency Testing

testing, sample parameters, sample concentration ranges, frequency of testing, and PT sample acceptance criteria. NELAC meets annually to evaluate the PT programs, collect input from the participants, their associated groups, and the regulated community, and revise the standards as needed. NELAC reviews and approves the PT sample acceptance criteria as described in Appendix C.

2.2.2 Proficiency Testing Study Providers

The providers shall produce and distribute PT samples, evaluate study results against published performance criteria, and report the results to the laboratories, the respective primary Accrediting Authorities, the appropriate PTOB, and NELAP. The PT Provider shall meet the requirements of Appendix A, manufacture samples that meet

the requirements of Appendix B, and score sample results in accordance with the requirements of Appendix C.

2.2.3 Proficiency Testing Oversight Body (PTOB)

The Proficiency Testing Oversight Body (PTOB) shall establish and implement a program to accredit PT study suppliers and to monitor accredited suppliers to ensure that their studies and practices meet all applicable standards. The PTOB shall meet the requirements of Appendix D. Organizations meeting the requirements of this Standard and its appendices, as determined by the NELAC Standing Committee on Proficiency Testing, may be nominated by the Committee to NELAP to be designated as a PTOB. NELAP may approve or disapprove the designation of an organization as a PTOB. The Committee may also recommentd to NELAP that a PTOB's designation be withdrawn for failing to meet the criteria in this standard and appendices.

2.2.4 Laboratories

Laboratories that seek to become accredited ~~by NELAP~~ shall perform analyses of PT samples as required by this chapter. PT samples shall be obtained from NELAP designated PTOB-~~NELAP A~~approved PT Providers. The laboratory shall obtain PT samples from any so ~~NELAP A~~approved PT Provider. The results of the analyses shall be submitted to the Provider for scoring. Accrediting Authorities shall accept for the purposes of initial and continuing accreditation, PT results from any NELAP approved provider that meets the requirements of this standard.

2.2.5 Accrediting Authorities (AA)

~~The States or the EPA Regions which hold primary Accrediting Authority are the Accrediting Authorities for those laboratories located within their respective boundaries.~~ The primary accrediting authorities shall make all decisions regarding a laboratory's accreditation status. They are responsible for taking action to make these determinations including ensuring that laboratories seeking or holding their accreditations are participating in the PT program.

2.3 REQUIREMENTS FOR PT PROVIDERS

This section and associated Appendix A describe the criteria that all PT providers shall meet in order to be approved by a ~~the~~ PTOB as PT Providers. A ~~The~~ PTOB shall grant approval

to PT providers on a field-of-testing basis, as described in Section 2.1.3.

2.3.1 On-Site Inspection of PT Providers

A ~~The~~ PTOB shall conduct an on-site inspection of any organization seeking to participate as a PT Provider in the NELAC Program, as described in Appendix D. The PTOBs shall determine whether the Provider meets the applicable requirements described in this Chapter and Appendices A, B, and C. Approval of a PT Provider shall be the responsibility of a ~~the~~ PTOB. A The PTOB shall conduct ongoing oversight of the PT Providers as necessary to ensure conformance with all applicable standards.

2.3.2 Sample Requirements and Design

This Section and associated Appendix B describe PT sample design and acceptance criteria. The matrices of all PT samples shall to the extent possible, resemble the matrices for which the laboratory seeks accreditation. Samples may not be reused.

2.3.2.1 Sample Analytes

The PT Provider shall prepare each sample lot such that the prepared ~~target~~ concentration of each analyte in each lot is unique. The required group of analytes in each sample covering each field of testing shall be determined by NELAC Standing Committee on Proficiency Testing and shall be evaluated and updated ~~annually~~, as necessary. ~~For a given field of testing, it is not necessary that every analyte be present in every study.~~ Within each study, a certain minimum number of analytes shall be present. The group of analytes included shall change over time so that all analytes are ~~eventually~~ included at least once every three years over a series of sequential studies.

2.3.2.2 Provider Sample Testing

The PT Provider shall design, manufacture, and test the samples for homogeneity, stability, and verification of prepared ~~target~~ values as required by Appendix B. This testing shall verify that the quality of all samples is acceptable for use in each field of testing PT study.

2.3.3 PT Study Data Analysis

This Section and associated Appendix C describe the criteria to be used by PT Providers when scoring and evaluating NELAC PT sample results.

~~**2.3.3.1 Data Set Size Requirements**~~

~~The PT Provider shall have enough participants to ensure that at least 20 valid data points are obtained for each analyte in each study. However, NELAP may waive this requirement for analytes that are analyzed infrequently by the laboratory community.~~

2.3.3.1~~2~~ Data Acceptance Criteria

PT Providers shall use the data acceptance criteria described in Appendix C to evaluate laboratories' PT data to ensure a laboratory's performance will be judged fairly and consistently.

2.3.4 Generation of Study Reports

Each PT study provider shall demonstrate that it can receive and evaluate the data and issue a report within 15 working ~~21 calendar~~ days of the close of each study.

2.3.5 Provider Conflict of Interest

Each PT study provider shall certify that it is free of any organizational conflict of interest. A PT sample producer shall never split a sample lot and offer these samples for sale as known-value check samples before the unknown samples are used in a PT study. In addition, each provider shall demonstrate that its security procedures are adequate to maintain confidentiality and security of all prepared ~~target~~ values through the closing date of each study. All records shall be retained for a period of five years or as required by the appropriate regulatory program.

2.3.6 Disapproval of PT Study Providers

A PT Provider's approval may be subjected to revocation per the procedures outlined in Appendix A, Section A.9.2 ~~shall be disapproved if documented deviations from the standard identified by the AA, the PTOB, or participating laboratories are not resolved within 30 calendar days after~~

~~the provider is notified in writing of the problem (Refer to Appendix A)~~.

2.3.7 PTOB Listing of PT Providers

~~The~~ PTOBs shall maintain a list of Approved PT Providers. ~~The~~ PTOBs shall evaluate, update, and publish this list at intervals not to exceed six months. On this same interval, The PTOB shall also publish the list of PT fields of testing necessary to satisfy the PT requirements as determined in Section 2.3.2.1.

2.4 LABORATORY ENROLLMENT IN PROFICIENCY TESTING PROGRAM(S)

2.4.1 Required Level of Participation

To be accredited initially and to maintain accreditation, each laboratory shall participate in a PT study provided by a PTOB-a~~A~~pproved PT Provider. Laboratories must request accreditation for a field of testing, as described in ~~Section 2.1.4 of this~~ Chapter 1. Each laboratory shall participate in at least two PT studies per year unless a different frequency for a given program is defined in the Appendices. The PT Provider shall design studies that require the analysis of one test sample for each field of testing. Section 2.5 describes the time period in which a laboratory must analyze the PT samples and report the results. Data and laboratory evaluation criteria are discussed in Sections 2.6 and 2.7 of this Chapter.

2.4.2 Requesting Accreditation

At the time each laboratory applies for accreditation, it shall notify the accrediting authority which field of testing ~~that~~ it chooses to complete to meet PT requirements. For all fields of testing, including those ~~tests~~ for which PT samples are not available, the laboratory shall ensure the reliability of its testing procedures by maintaining a total quality management system that meets all applicable requirements of Chapter 5 of the NELAC standards.

2.4.3 Reporting Results

Laboratories seeking accreditation may select any provider from the list of PTOB-a~~A~~pproved PT study providers. The laboratories shall bear the cost of any PT study

subscription. Each laboratory shall authorize the PT study provider to release all accreditation and remediation ~~report its~~ results and pass/fail status directly to the appropriate accrediting authority, NELAP and the PTOB, in addition to the laboratory.

2.5 REQUIREMENTS FOR LABORATORY TESTING OF PT STUDY SAMPLES

A laboratory must participate in two ~~PTOB-approved~~ single-blind, single-concentration PT studies provided by a PTOB-approved PT provider per year for each field of testing for which it seeks or wants to maintain accreditation. The samples shall be analyzed and the results returned to the PT study provider no later than ~~30~~ ~~45 calendar~~ 30 working days from ~~the date of sample receipt~~ the scheduled study shipment date. The laboratory's management and all analysts shall ensure that all PT samples are handled (i.e., managed, analyzed, and reported) in the same manner as real environmental samples ~~to the extent possible. The laboratory shall utilize the same staff, procedures, equipment, facilities, and frequency of analysis for PT samples as for real environmental samples~~ utilizing the same staff, methods, procedures, equipment, facilities, and frequency of analysis.

2.5.1 Restrictions on Exchanging Information

Laboratories shall comply with the following restrictions on the transfer of PT samples and communication of PT sample results prior to the time the results of the study are released:

a) A laboratory shall not send any PT sample, or a portion of a PT sample, to another laboratory for any analysis for which it seeks accreditation~~;~~, or is accredited.

b) A laboratory shall not knowingly receive any PT sample or portion of a PT sample from another laboratory for any analysis for which the sending laboratory seeks accreditation;

c) A laboratory shall not allow management or staff to communicate with any individual at another laboratory (including intracompany communication) concerning the PT sample; and

d) Laboratory management and staff shall not attempt to obtain the prepared ~~target~~ value of any PT sample from their PT provider.

2.5.2 Maintenance of Records

The laboratory shall maintain copies of all written, printed, and electronic records, including but not limited to bench sheets, instrument strip charts or printouts, data calculations, and data reports, resulting from the analysis of any PT sample for five years or for as long as is required by the applicable regulatory program, whichever is greater. These records shall include a copy of the PT study report forms used by the laboratory to record PT results. All of these laboratory records shall be made available to the assessors of the primary accrediting authority during on-site audits of the laboratory.

2.6 EVALUATION OF PROFICIENCY TESTING RESULTS

~~Program specific criteria apply where available, but in the absence of specific criteria established by the appropriate EPA program offices the criteria presented in this section and associated Appendix C are considered to be NELAC defaults that would apply.~~

~~2.6.1 Scoring of Laboratory PT Sample Results~~

PT study providers shall evaluate results from all PT studies using NELAC-mandated acceptance criteria ~~as~~ described in Appendix C. The NELAC Standing Committee on Proficiency Testing shall provide, ~~(~~ and update as necessary ~~on an annual basis)~~, the data acceptance criteria that all PT study providers shall use for all PT ~~study data~~ studies. Each result will be scored on an acceptable/not acceptable basis. The PT study provider will provide the participant laboratories and the primary ~~the~~ accrediting authority~~, the PTOB, and NELAP~~ a report showing at least the ~~target~~ prepared value, the acceptance range, and the acceptable/not acceptable status for each analyte ~~for each~~ reported by the laboratory ~~participant~~. The report shall be sent no later than ~~21 calender~~ 15 working days from the study closing date. The providers shall not disclose specific laboratory results or evaluations to any other parties not described in this section.

2.7 PT CRITERIA FOR LABORATORY ACCREDITATION

The criteria presented in this section and associated Appendix C are considered to be NELAC defaults that would apply in the absence of specific ~~criteria~~ program regulations established by the appropriate EPA program offices. ~~The various EPA program offices may choose to establish their own program-specific criteria.~~

2.7.1 Result Categories

The criteria described in this section apply individually to each field of testing, as defined by the laboratory seeking accreditation in its accreditation request. These criteria apply only to the PT portion of the overall accreditation standard, and the accrediting authority will consider PT results along with the other elements of the NELAC standards when determining a laboratory's accreditation status. The accrediting authority ultimately makes all decisions regarding the accreditation status of the laboratory. There are two PT result categories: "acceptable" and "not acceptable."

2.7.2 Initial and Continuing Accreditation

A laboratory ~~which~~ seek~~s~~ing accreditation shall successfully complete two PT studies for each requested field of testing within the most recent three rounds attempted. Successful performance is described in Appendix C. Once a laboratory has been granted accreditation status, it must continue to complete PT studies and maintain a history of at least two ~~successful~~ acceptable studies out of the most recent three. For either initial or continuing accreditation, completion dates of successive proficiency testing rounds for a given field of study must be at least semiannual (i.e., not more than six months apart) but must be at least ~~30 calendar~~ 20 working days apart (i.e., participation in a second study or a remedial study may not occur within ~~30 calendar~~ 20 working days of the first or failed study). Failure to meet the semiannual schedule is regarded as a failed study.

2.7.3 Supplemental Studies

A laboratory may elect to ~~conduct~~ participate in PT studies more frequently than required by the semiannual schedule as set by the primary accrediting authority. This may be desirable, for example, when a laboratory first applies for accreditation or when a laboratory fails a study and wishes

to quickly re-establish its history of successful performance. These additional studies are not distinguished from the routinely scheduled studies; that is, they are counted and scored the same way. ~~Periodic PT studies will occur at fixed times per year (schedule to be determined). Initial and remedial samples can be obtained at other times.~~

2.7.4 Failed Studies and Corrective Action

Whenever a laboratory fails a study, it shall determine the cause for the failure and take any necessary corrective action. It shall then document in its own records both the investigation and the action taken. If a laboratory fails two out of the three most recent studies for a given field of testing, its performance is considered unacceptable under the NELAC PT standard for that field. The laboratory must then meet the requirements of initial accreditation as described in Section 2.7.2 - Initial and Continuing Accreditation.

2.7.5 Second Failed Study

The PT Provider reports laboratory PT performance results to the accrediting authority at the same time that it reports the results to the laboratory. If a laboratory fails a second study out of the most recent three, as described above, the accrediting authority shall take action within ~~60 calendar~~ 40 working days to revoke ~~determine~~ the accreditation status of all methods for the unacceptable analyte(s). ~~capability of the laboratory to meet accreditation requirements. The accrediting authority shall review the accreditation status of all methods related to the analyte(s). in the failed study, and not just the method by which the failed PT was analyzed.~~

2.7.6 Scheduling of PT Studies

Primary accrediting authorities may specify the months that laboratories within its authority are required to participate in NELAC PT programs.

APPENDIX A

PT PROVIDER APPROVAL CRITERIA

A.0.0 SCOPE

This Appendix describes the responsibilities and requirements a Proficiency Testing (PT) Provider shall meet in order to be a Proficiency Testing Oversight Body (PTOB) Approved PT Provider. In order for a PT Provider to participate in the NELAC PT Program, a Provider must be approved by a ~~the~~ PTOB. The criteria provided below are designated to ensure the integrity and technical excellence of the NELAC PT Program while allowing all qualified Providers to participate in the program.

A.1.0 APPROVAL PROCESS

The process for approval of a PT Provider includes a biannual on-site inspection by a ~~the~~ PTOB to ensure that the technical criteria of this appendix are being met. At the discretion of the PTOB, the PT Provider may be requested to confirm their ability to perform analyses within the required limits through participation in a proficiency testing program operated by the PTOB, or through the analysis of unknown samples provided by the PTOB. Providers are also required to submit the results of PT programs operated for NELAC to the PTOB for review and evaluation. The PT Provider agrees to accept the findings and decisions of the PTOB as final.

A.2.0 QUALITY SYSTEM REQUIREMENTS

The manufacturing quality system used by the PT Provider must meet the requirements of both International Organization for Standardization (ISO) 9001 for the design, production, testing, and distribution of performance evaluation samples and the requirements of ISO Guide 34 Quality System Guidelines for the Production of Reference Materials. The design and operation of the PT Provider's proficiency testing program must meet the requirements of ISO Guide 43, Proficiency Testing by Interlaboratory Comparisons. The testing facilities used to support the verification, homogeneity, and stability testing required in Appendix B of this document must meet the requirements of both ISO Guide 25 General Requirements for the Competency of Testing and Calibration Laboratories and Chapter 5, Quality Systems, of the NELAC standards. ~~for the quality of testing facilities.~~ The ability to meet the ISO 9001 quality system requirement may be fulfilled through registration of the PT Provider's quality system to~~by an~~ American National

Standards Institute (ANSI) standards by a Registrar Accreditation Board (RAB) accredited registrar. However, ~~a~~an biannual on-site inspection by the PTOB demonstrating continuing conformance~~performance~~ is required.

A.3.0 PROVIDER FACILITIES AND PERSONNEL

Each Provider is required to have systems in place to produce, test, distribute, and provide data analysis and reporting functions for any series of samples for which they are requesting approval. Similarly, the Provider shall have in place sufficient technical staff, instrumentation, and computer capabilities as may be required by the PTOB to support the production, distribution, analysis, data collection, data analysis, and reporting functions of the samples. No portion of the production, testing, distribution, data collection, data analysis, nor data reporting functions may be outside the control of the PT Provider for any particular study, since it is essential that the confidentiality of the samples be maintained throughout the PT study. For the purposes of this requirement "control" can mean ownership or that the subcontracted service is performed under an agreement which specifically ensures the ability of the Provider to access and restrict the distribution of information related to these services. Any subcontracted services must be assessed by a PTOB and meet the same criteria as the PT Provider.

A.4.0 SAMPLE ~~DESIGN~~FORMULATION REVIEW

The PT Provider must demonstrate to the PTOB, by the submission of appropriate data, that the sample ~~design~~formulation for which the PT Provider is seeking approval will permit participating laboratories to generate results that fall within the sample acceptance ranges established by the NELAC ~~or the PTOB~~ Standing Committee on Proficiency Testing and meet the criteria of the National Standards for Proficiency Testing.

A.4.1 RELEASE OF INFORMATION

In support of the above requirement, ~~the~~ PTOBs agree~~s~~ to treat all sample ~~design~~formulation information submitted to them for review as the proprietary information of the PT Provider submitting the information. Such ~~design~~formulation information shall not be released by a ~~the~~ PTOB without the prior written consent of the PT Provider.

A.5.0 PROVIDER CONFLICT-OF-INTEREST REQUIREMENTS

PT Providers seeking approval shall document to the satisfaction of the PTOB that they do not have a conflict-of-interest with any laboratory seeking, or having, NELAP~~C~~ accreditation. PT Providers shall notify the PTOB of any actual or potential organizational conflicts of interest, including but not limited to:

a) Any financial interest in a laboratory seeking, or having, NELAP~~C~~ accreditation;

b) The sharing of personnel, facilities or instrumentation with a laboratory seeking, or having, NELAP~~C~~ accreditation.

The PT Provider is also required to inform all internal and contract personnel who perform work on NELAC PT samples of their obligation to report personal and organizational conflicts of interest to the PTOB. The Provider shall have a continuing obligation to identify and report any actual or potential conflicts of interest arising during the performance of work in support of NELAC PT programs. If an actual or potential organizational conflict of interest is identified during performance of work in support of NELAC PT programs, the PT Provider shall immediately make a full disclosure to the PTOB. The disclosure shall include a description of any action which the Provider has taken or proposes to take, after consultation with the PTOB, to avoid, mitigate or neutralize the actual or potential conflict of interest. The PTOB may reevaluate a PT Provider's Approval status as a result of unresolved conflict of interest situations. Any conflict of interest disputes between the PT Provider and the PTOB may be appealed to NELAP for a final determination.

A.5.1 BAN ON DISTRIBUTION OF SAMPLES

~~Furthermore,~~ PT Providers shall not sell, distribute, or provide samples used in the NELAC PT program prior to the conclusion of the study for which they were designed. Providers further agree not to sell, distribute, or provide samples of identical ~~design~~formulation and concentration to those samples which it is currently using in a NELAC study.

A.6.0 CONFIDENTIALITY OF PT STUDY DATA

The PT Provider shall demonstrate to the PTOB that is has systems in place to ensure that the confidentiality of data associated with NELAC PT samples and programs are ~~is~~ not compromised. PT Providers shall not release the ~~Target~~Prepared Value of any sample currently being used in a NELAC PT study prior to the conclusion of the study. The PT Provider also agrees that the acceptance ranges provided to them by either NELAC, or the PTOB, are the proprietary information of NELAC, or the PTOB, and shall not be disclosed by the PT Provider without the written approval of the PTOB.

A.7.0 DATA REVIEW AND EVALUATION

The NELAP designated ~~Approved~~ PTOB will review the data from every PT Provider's studies~~y~~ to ensure that acceptance limits used to evaluate laboratories are consistent with national standards as established by NELAC. The PTOB will also evaluate the performance of the PT Providers by monitoring, and reporting, to both and the Providers and the NELAC Standing Committee on Proficiency Testing the pass/fail rates of all Providers on all samples tested. A ~~The~~ PTOB is required to investigate any PT Provider whose pass/fail rate is statistically different from the national average.

A.8.0 COMPLAINTS & CORRECTIVE ACTION

Written complaints received by the PT Provider regarding technical or procedural aspects of the studies they conduct~~their performance in the NELAP PT program~~ must be submitted to the PTOB within ~~seven calendar~~ five (5) working days from receipt of the complaint by the PT Provider. The PT Provider shall resolve the complaint to the satisfaction of the PTOB within ~~30 calendar~~ 20 working days from the date received by the PTOB. The PTOB is the sole judge of the adequacy of the corrective action taken by the PT Provider. ~~It is the responsibility of T~~the PTOB will~~to~~ provide NELAP with an annual summary of all PT Provider complaints received during the prior year.

A.9.0 LOSS OF PROVIDER APPROVAL

PT Providers who fail to meet the requirements of these standards~~is appendix or those of Appendix B,~~ may be subject to loss of their approval as a NELAC PT Provider. Providers may lose approval to provide individual sample sets based

upon review of PT study data by a ~~the~~ PTOB as required in Appendix A, Section A.7. Similarly, PT Providers who fail to meet the requirements of Appendix A, Sections A2 through A6, on a continuous basis may lose their approval as a PTOB-a~~A~~pproved PT Provider for all samples.

A.9.1 PERIODIC REVIEW OF PT PROVIDERS

A ~~The~~ PTOB may at any time, review the performance of any approved PT Provider against these standards ~~terms and conditions of both Appendix A and Appendix B~~. Based upon this review, the PTOB may decide~~determine~~ that the approval status of a PT Provider be revoked, adjusted, limited, or otherwise changed based upon failure to meet one or more of the specified requirements.

A.9.2 REVOCATION OF APPROVAL

A ~~The~~ PTOB may take any of the following actions in response to its determination that a PT Provider's approval status should change:

a) If the PT Provider fails to meet the requirements of Appendix B for a particular sample set, or series of sample sets, a ~~the~~ PTOB may revoke approval of the PT Provider to provide these sample sets for the NELAC PT program. PT Providers may request reapproval for the sample sets by verifying to the PTOB that the problem has been corrected.

b) If the PT Provider fails to meet the requirements of Appendix A, Section A2 or A3, a ~~the~~ PTOB may revoke the PT Provider's approval to supply any samples under the NELAC PT program until such time that the PT Provider corrects the problem and the PTOB verifies through an on-site inspection that the corrective action has been effective.

c) If the PT Provider fails to meet the requirements of Appendix A, Sections A5 through A6, a ~~the~~ PTOB may revoke the PT Provider's approval ~~to supply any samples~~ under the NELAC PT program. In this case, the PT Provider may not reapply for reapproval for a period of three years from the date of revocation of approval.

APPENDIX B

PT SAMPLE DESIGN & ACCEPTANCE GUIDELINES

B.0.0 INTRODUCTION

An integral element of the NELAC PT Program Standards is the assurance of PT samples which are of high quality, well documented, homogeneous, and stable. In order to meet the goals of NELAC, the PT samples used in the program must also provide all laboratories with samples which offer a consistent challenge. All PT samples must meet all applicable specifications of these standards ~~by EPA and/or NELAC~~.

B.1.0 VERIFICATION OF PREPARED ~~TARGET~~ VALUE

All PT samples used in the NELAC program must be analyzed by the PT provider prior to shipment to the laboratories to ensure suitability for use in the program. The Prepared ~~Target~~ Value of the sample will be used to establish acceptance criteria, and it must be verified by analysis. PT providers must verify the Prepared ~~Target~~ Value by direct analysis against National Institute of Standards and Technology (NIST) Standard Reference Materials (SRM), if a suitable NIST SRM is available for use. If a NIST SRM is not available then verification must be performed against an independently prepared calibration material. An independently prepared calibrant is one prepared from a separate raw material source, or one prepared and documented by a source external to the provider.

B.1.1 RELATIVE STANDARD DEVIATION OF VERIFICATION

The method used by the PT provider for verification analysis must have a relative standard deviation of not more than 50%~~fifty percent~~ of the relative standard deviation predicted at the Prepared Value by the laboratory acceptance criteria being used by NELAC for each parameter. The relative standard deviation of the provider's verification method shall ~~will~~ be established by a method validation study, and the suitability for use shall ~~will~~ be approved by the NELAP designated Proficiency Testing Oversight Body (PTOB).

B.1.2 VERIFICATION OF THE PREPARED VALUE

The prepared value for e~~E~~very parameter in all PT samples must be verified by analysis. The prepared value ~~Target Value~~ of the analyte ~~sample~~ is verified if the mean of the verification analyses is within 1.5 standard deviations, as

calculated as described in Sections C.1.1.1 or C.1.1.2, of either a) the prepared value if an unbiased verification method is used or b) the mean value for the analyte as calculated in Sections C.1.1.1 or C.1.1.2 if a biased method is used. ~~Target Value of the sample fall within a 99% Confidence Interval calculated from the Mean and Standard Deviation of the data generated during the verification analysis.~~ The standard deviation of the verification analyses also must be less than one standard deviation as calculated in Sections C.1.1.1 or C.1.1.2. For analytes that are evaluated using fixed percentages as defined in Section C.1.1.1, standard deviations are calculated by assuming that the fixed percentage is equal to two standard deviations.

B.2.0 HOMOGENEITY TESTING ~~VERIFICATION~~

PT sample homogeneity is essential to ensuring that all laboratories are treated fairly. Therefore, the purpose of the homogeneity testing procedure is to establish at the 95% confidence level ~~ensure that within a 95% Confidence Limit~~ that all samples distributed to the laboratories have the same Prepared ~~Target~~ Value for every parameter to be evaluated. Homogeneity testing is required on all PT samples prior to sample shipment to the laboratories.

B.2.1 HOMOGENEITY TESTING PROCEDURE

The homogeneity of the samples must be established using a generally accepted statistical procedure. The procedure selected by the PT provider must be capable of evaluating the relative consistency of each analyte across the production run, and must be performed on the final packaged samples. The procedure must establish at the ~~within a~~ 95% c~~C~~onfidence level ~~Limit~~ that the Prepared ~~Target~~ Value is consistent across the production run. Samples, or parameters, which fail to pass the homogeneity testing criteria ~~of the procedure used by the PT provider at the 95% Confidence Interval~~ cannot be used in the NELAC PT program to evaluate~~d~~ laboratories.

B.2.2 SUITABLE HOMOGENEITY TESTING PROCEDURES

A suitable homogeneity testing procedure will be capable of comparing the between ~~within~~ sample to within ~~between~~ sample standard deviation across the PT provider's packaging run, and will ensure comparability with~~in a~~ 95% c~~C~~onfidence

~~Interval~~. Suitable homogeneity testing procedures are available in both ISO Guide 35 for the Certification of Reference Materials and in the ISC Reference Material Committee (REMCO)-Association of Official Analytical Chemists (~~/~~AOAC) Harmonized Protocol for the Proficiency Testing of Analytical Laboratories. However, the homogeneity testing procedure used by the PT provider must be approved for use by the PTOB.

B.3.0 STABILITY TESTING

The samples used in the NELAC PT program must ~~to~~ be verified as stable for the period of each study. Therefore, the stability of all samples, and parameters, must be established by the PT provider following the close of data submission from the laboratories. The samples are considered stable for the period of the study if the Mean analytical value as determined after the study for each parameter falls within the 99% Confidence Interval calculated for the prior to shipment verification testing used to establish ~~verify~~ the Prepared ~~Target~~ Value. The testing procedure used for stability testing must be approved for use by the PTOB.

B.4.0 SAMPLE FORMULATION ~~DESIGN~~ APPROVAL

The sample formulation ~~design~~ for each sample used in the NELAC PT program must be evaluated, and approved for use, by the PTOB prior to their use in the NELAC program. The criteria for formulation ~~design~~ adequacy are that the sample will provide equivalent challenge to the laboratories under test as similar samples for the same parameters as other providers, and that the sample will exhibit laboratory acceptance rates, measured as provider percentage pass/fail performance, consistent with other samples used in the program for the same parameters.

B.4.1 ADEQUACY OF THE SAMPLE DESIGN

The testing and verification protocol required to establish sample equivalency will be agreed to by both the PT provider and the PTOB on a case by case basis. It is the responsibility of the PT provider to demonstrate the adequacy of sample design to the satisfaction of the PTOB.

B.5.0 DATA REPORTING BY PT PROVIDERS

The results of sample Prepared ~~Target~~ Value verification, homogeneity, and stability testing must be available to the participating laboratories. All data developed by the provider in support of verification testing, homogeneity testing, and stability analysis must be provided to any laboratory participating in the program upon request after the close of the study.

B.5.1

The data developed by the PT provider in support of verification, homogeneity, and stability testing will be supplied in summary format to the PTOB in an electronic format to be determined by the PTOB. Verification and homogeneity data must be supplied to the PTOB prior to sample distribution to the laboratories.

B.5.2

All data from the laboratories and the results of stability testing must be provided to the PTOB in an electronic format to be determined by the PTOB within ~~30 calendar thirty~~ 20 working days of the close of the study.

APPENDIX C

PT ACCEPTANCE CRITERIA
AND
PT PASS/FAIL CRITERIA

C.0.0 PURPOSE, SCOPE, AND APPLICABILITY

This Appendix defines the criteria to be used by any entity which seeks to participate as a Proficiency Test Provider in the NELAC Program for scoring the results obtained from the analyses of samples in any NELAC PT Study. Two distinct sets of scoring criteria are defined: 1) whether or not an individual analyte result is either "Acceptable" or "Not Acceptable" and 2) whether or not a laboratory's initial PT performance for a group of interdependent analytes can be evaluated as "Pass" or "Fail". The PT Providers shall submit all laboratories' performance rating(s) to the Primary Accrediting Authority, as described in Chapter 2 of the NELAC standards, to be used as a tool for determining a laboratory's ~~NELAP~~ accreditation status. PT acceptance limits and pass/fail criteria are established on a Program-matrix-analyte basis ~~according to PT fields of testing, which are defined in Chapter 2 of the NELAC standards~~.

C.1.0 ANALYTE ACCEPTANCE LIMITS

Acceptance limits are established for each ~~individual~~ analyte. Whether or not a laboratory has passed or failed a group of interdependent analytes is based on the number of results that are determined to be acceptable.

C.1.1 Analyte Acceptance Limit Categories

Acceptance limits are separated into three categories. Results for analytes with acceptance limits determined as described in Sections C.1.1.1 and C.1.1.2 will be used in the determination of a laboratory's Program-matrix-analyte ~~PT Field of Testing~~ pass/fail evaluation. Results for analytes with acceptance limits determined as described in Section C.1.1.3 will not be used as part of the ~~PT Field of Testing~~ Program-matrix-analyte pass/fail evaluation.

C.1.1.1 Analytes with EPA Promulgated Acceptance Limits

PT Providers shall utilize the proficiency test acceptance limits that have been promulgated in regulations ~~or guidelines by EPA programs~~. The most recent EPA regulations ~~and/or guidelines~~ are incorporated into this Appendix by reference. EPA's promulgated proficiency test acceptance limits for chemical analytes are typically expressed in the following manner:

- **Prepared ~~Target ±~~ fixed percentage.** Acceptance limits shall be set at plus and minus the published fixed percentage of the analyte's verified prepared ~~validated target~~ value.

- **Mean ± 2 standard deviations.** For those analytes for which the NELAC Standing Committee on Proficiency Testing ~~PTOB~~ has established linear regression equations relating prepared ~~target~~ value to mean and prepared ~~target~~ value to standard deviation, acceptance limits shall be set using said equations and the sample's verified prepared ~~validated target~~ value. Linear regression equations may only be used for prepared ~~target~~ values that fall within the range of prepared ~~target~~ values used to establish said equations. In the event that there are no linear regression equations available for a given analyte, that analyte will be treated as described in Section C.1.1.3.

C.1.1.2 Analytes with acceptance limits derived from regression equations established by the NELAC Standing Committee on Proficiency Testing ~~PTOB and approved by the NELAC~~

When EPA Program regulations ~~or guidance~~ for establishing acceptance criteria are not available Proficiency Test providers shall set acceptance limits ~~as follows. R~~ using regression equations that predict the mean and standard deviation for an analyte in a given range of concentrations. ~~in PT samples~~ Regression equations will be derived by the NELAC Standing Committee on Proficiency Testing and will be made available to PTOB-approved PT Providers by the PT Committee Chair or the Executive Director of NELAP ~~PTOB~~. Data from sources such as the EPA PE studies, interlaboratory results from professional organizations such as ASTM, other proficiency testing providers, commercial and non-profit organizations, will be used to establish the equations. All regression equations shall ~~will~~ be approved by the NELAC Standing Committee on Proficiency Testing prior to use by a PTOB-a~~A~~pproved PT P~~p~~rovider. For these analytes, the PT Provider shall use the sample's verified prepared ~~validated target~~ value and said equations to determine the mean and standard deviation. ~~The regression equations shall be designed to be applicable across the NELAC designated PT concentration range.~~

C.1.1.3 Experimental Data: Analytes without promulgated acceptance limits or ~~EPA~~ established regression equations~~, i.e., "Experimental Data"~~

For those analytes not included in categories C.1.1.1 or C.1.1.2, e.g., newly regulated analytes, or analytes in a matrix that have not been fully evaluated in interlaboratory studies, NELAC acceptance limits will be established only after interlaboratory data has been collected for a minimum of one year unless the NELAC Standing Committee on Proficiency Testing ~~PTOB~~ determines that sufficient data have been collected in less time. The data obtained during the one-year period shall be referred to as "experimental data". ~~NELAC with the assistance of t~~The NELAC Standing Committee on Proficiency Testing ~~Oversight Body,~~ will derive regression equations to be used to establish acceptance limits for analytes in the experimental category after sufficient data have been collected. The laboratory will receive a copy of its own experimental data from the PT Provider at the conclusion of the PT study.

C.2.0 ACCEPTABLE PT RESULTS FOR CHEMICAL ANALYTES IN POTABLE WATER AND~~,~~ NON-POTABLE WATER ~~AND HAZARDOUS WASTE~~ PT SAMPLES

A laboratory's PT analyte result is a~~A~~cceptable when it falls within the regulatory ~~EPA's~~ promulgated acceptance limits (Section C.1.1.1). For Section C.1.1.2 analytes, PT Providers shall use the PT sample's verified prepared ~~validated target~~ value and said regression equations to determine the mean and standard deviation. Acceptance limits shall be set at the ~~99% prediction interval based on the~~ mean ± two ~~and~~ standard deviations for potable water analytes and the mean ± three standard deviations for non-potable water analytes. A result is a~~A~~cceptable when it falls within these derived acceptance limits.

C.3.0 NOT ACCEPTABLE PT RESULTS FOR POTABLE WATER AND~~,~~ NON-POTABLE WATER ~~AND HAZARDOUS WASTE~~ PT SAMPLES

A laboratory's result for any analyte is considered unacceptable if it meets any of the following criteria:

a) The result falls outside the EPA's promulgated acceptance limits (Section C.1.1.1) or outside ~~the 99%~~ prediction interval derived from ~~PTOB~~ established regression equations (Section C.~~1.1.~~2.0);

b) The lab reports a result for an analyte not present in the PT sample (i.e., a false positive);

c) The lab reports a result of "Not Detected", (or similar indication of no detection), for an analyte present in the PT sample (i.e., a false negative);

NOTE: False positives and false negatives will only be scored "not acceptable" when an analyte has an EPA promulgated required detection limit (RDL). For example if a laboratory reports a result above the EPA promulgated RDL for a given analyte that is not present in the PT sample, then the result will be classified as a false positive and scored as "not acceptable". Conversely, if a laboratory reports a result less then the RDL for an analyte present in the PT sample at a concentration within the NELAC-approved PT concentration range, the result will be classified as a false negative and scored as "not acceptable".

d) The lab fails to submit its results to the PT Provider on or before the deadline for the PT study.

C.4.0 ADDITIONAL REQUIREMENTS FOR PT PROVIDERS

PT Providers shall examine all data sets for bimodal distribution and/or situations where results from a given method have disproportionally large failure rates or reporting anomalies to the Proficiency Testing Oversight Body. All proficiency test data are to be submitted to the PTOB in the format specified by the PTOB and shall be reviewed annually by the NELAC Standing Committee for Proficiency Testing ~~in conjunction with the EPA~~ for the purpose of revising existing and establishing new linear regression equations.

C.5.0 NELAC PT STUDY PASS/FAIL CRITERIA

NELAC PT samples are designed to meet the requirements of Chapter 2 and associated appendices. Once data acceptability has been determined as described in Sections C.1 through C.3 of this appendix, the laboratory's PT "Pass" or "Fail" evaluation is determined as described in this Section. Pass/Fail criteria are used when groups of

interdependent analytes are evaluated as a unit for the laboratory's initial demonstration of proficiency.

C.5.1 Interdependent Analyte Pt Samples

Interdependent analyte PT Samples are those that are analyzed using methods in which the ability to correctly identify and quantitate a series of analytes is indicative of the laboratory's ability to correctly determine the presence or absence of similar analytes. Examples of interdependent PT Samples are those used for the following series of analytes; volatiles, semivolatiles, pesticides, herbicides, etc..

C.5.2 Non-interdependent Analyte Pt Samples

Non-interdependent PT Samples are those that are analyzed using methods in which the ability to correctly identify and quantitate an analyte or a series of analytes in a sample is not indicative of the laboratory's ability to correctly identify and quantitate similar analytes. Non-interdependent analyte PT samples may contain a single analyte, e.g., pH, BOD, TSS, etc., or may contain multiple analytes, e.g., metals, major ions, etc.

C.5.3 Promulgated Epa Pass/fail Criteria

In all cases, promulgated EPA pass/fail criteria, e.g., drinking water volatiles as listed in 40 CFR 141.61(a), subsection (m)(1), will be used as NELAC PT pass/fail criteria as applicable. The criteria described in ~~the following~~ Section~~s,~~ 5.4 ~~and 5.5,~~ shall be used in the absence of promulgated EPA pass/fail guidelines.

C.5.4 Pass/fail Criteria For Interdependent Analyte Pt Samples

Proficiency Testing pass/fail evaluations for Interdependent Analyte PT samples shall be determined as follows. To receive a score of "Pass", a laboratory must produce "Acceptable" results as defined in Section C.1 for 80% of the analytes in an Interdependent Analyte PT Sample. Greater than 20% "Not Acceptable" results will result in the laboratory receiving a score of "Fail" for that series of analytes. For example, a laboratory must report all "Acceptable" results for an Interdependent Analyte PT Sample containing 1-4 analytes, may report no more then one

"Not Acceptable" result for a Sample containing 5-9 analytes, two "Not Acceptable" results for a Sample containing 10-14 analytes, etc A "Not Acceptable" result for the same analyte in two consecutive PT studies will also result in the laboratory receiving a score of "Fail" for that analyte.

~~**C.5.5 PASS/FAIL CRITERIA FOR NON-INTERDEPENDENT ANALYTE PT SAMPLES**~~

~~To receive a score of "Pass", a laboratory must produce "Acceptable" results as defined in Section C.1 for all analytes in a Non-Interdependent Analyte PT Sample. One or more "Not Acceptable" results will result in the laboratory receiving a score of "Fail" for that Field of Testing sample.~~

APPENDIX D

PT OVERSIGHT BODY

D.0.0 PURPOSE, SCOPE, AND APPLICABILITY

This Appendix defines the qualifications, scope of responsibilities and requirements for a ~~the~~ NELAP~~C~~ designated Proficiency Testing Oversight Body (PTOB) as defined in Section 2.2.3 of the NELAC document. In addition to complying with the requirements of this Appendix, a ~~the~~ PTOB, for this oversight function, shall comply with the applicable requirements described in Chapter 2 and associated Appendices A (PT Provider Acceptance Criteria), B (PT Sample Design and Acceptance Guidelines), and C (Criteria for Setting PT Data Acceptance Limits).

D.1.0 TECHNICAL AND ADMINISTRATIVE QUALIFICATIONS

An organizaion ~~The PTOB~~ shall demonstrate to ~~NELAP~~ the NELAC Standing Committee on Proficiency Testing by the submission of a current Statement of Qualifications that it has the technical expertise, administrative capacity, and financial resources sufficient to implement and operate a national program of PT Provider evaluation and oversight. In the event that the organization ~~PTOB~~ is not a nationally or internationally recognized authority, the NELAC Standing Committee on Proficiency Testing reserves the right to request further documentation detailing the organization~~PTOB~~'s qualifications. The organization ~~PTOB~~ shall meet the following general requirements:

a) ~~The PTOB shall d~~Demonstrate the capability to manage and evaluate complex environmental reference materials in a variety of matrices;

b) ~~The PTOB shall d~~Demonstrate expertise in statistical applications as related to large interlaboratory performance evaluation programs;

c) ~~The PTOB shall d~~Demonstrate the capability to conduct on-site audits of PT Providers;

d) ~~The PTOB shall d~~Demonstrate the capability to conduct technical reviews of Initial Applications;

e) ~~The PTOB shall d~~Demonstrate a knowledge and understanding of the ISO guides 9001, 34, 43, and Chapter 2 of the NELAC standards including Appendices A, B, and C.

D.2.0 PTOB RESPONSIBILITIES REGARDING INITIAL ASSESSMENT OF PT PROVIDERS

~~The~~ PTOB responsibilities are described in this section. The primary responsibility of a ~~the~~ PTOB is the oversight and ongoing monitoring and evaluation of the PT Providers. The oversight activities of a ~~the~~ PTOB shall be designed to ensure that the PT Provider meets the requirements specified in Chapter 2 and Appendices A, B and C. Any variations from these requirements shall be approved by NELAC prior to a body being approved as a NELAC PTOB. All activities described herein shall be conducted by a ~~the~~ PTOB.

D.2.1 Development of Standard Operating Procedures and Forms

~~The~~ PTOBs shall develop the Standard Operating Procedures (SOPs) necessary to conduct the PT Provider evaluation process. These documents shall be based upon the requirements of Chapter 2 of the NELAC standards and the associated Appendices A, B, and C. The NELA~~P~~C Standing Committee on Proficiency Testing has the authority to review and approve, as necessary, the SOPs developed by a ~~the~~ PTOB.

D.2.1.1 SOP(s) for the Assessment Process

The PTOB shall develop and implement SOP(s) including but not limited to: the initial application submittal and review process, on site inspection, submittal of final reports to NELAP, the procedures for det~~y~~ermining that a PT Provider's approval be revoked, the procedures for appealing approval determinations, and any other procedures deemed necessary by NELAC.

D.2.1.2 Initial Application

A ~~The~~ PTOB shall develop the initial application process to be submitted by ~~all~~ PT Providers applying for approval as PT Providers of NELAC samples. The application shall include questions regarding the qualifications of the organization seeking approval. In addition to completing the initial application process, a ~~the~~ PTOB shall require that the PT Provider submit copies of its current ISO 9001 registration certificate or any other documents which detail the quality systems required by the provisions of Chapter 2 and associated Appendices.

D.2.1.3 SOP(s) for On-Site Inspections and Checklist(s)

A ~~The~~ PTOB shall develop SOP(s) for conducting consistent, effective, on-site inspections of PT Providers. The SOP shall include policies which describe the circumstances for conducting any additional inspections, and circumstances for determining whether on-site inspections will be announced or unannounced. A ~~The~~ PTOB shall develop standard, consistent checklist(s) to be used during any and all inspections of PT Providers.

D.2.2 Initial Application Review and On-site Inspections

A ~~The~~ PTOB shall follow the procedures described in this section for the review of applications and on-site inspections of any candidate PT Provider.

a) A ~~The~~ PTOB shall review the initial application documents, described in D.2.1.2, for compliance with the PT Provider qualifications described in Appendix A and other applicable documents.

b) A ~~The~~ PTOB shall review the sample designs used by the PT Provider for compliance with Appendix B and other applicable documents.

c) A ~~The~~ PTOB shall review the PT analyte and sample scoring procedures used by the PT Provider for compliance with Appendix C and other applicable documents.

d) No later than ~~ninety (90) calendar~~ sixty five (65) working days after the review of the Initial Application and associated documents, a ~~the~~ PTOB shall conduct an on-site inspection of the PT Provider. The PT Provider shall be provided with checklist(s) to be used during the inspection as part of the initial application process. The inspection may be conducted more than ~~90~~65 working days after reviewing the initial application only if unforeseen circumstances beyond the control of a ~~the~~ PTOB, prevent an inspection from being conducted within this time period. The inspection shall be conducted following the SOP(s) and documented on the checklist(s) described in Section D.2.1.3.

e) Following the inspection, a ~~the~~ PTOB shall conduct an exit meeting with the PT Provider, which shall include

discussion of deficiencies and discrepancies found; however, a ~~the~~ PTOB may further revise the findings after the closing of the exit meeting, if necessary.

The inspection shall include, at a minimum:

1) Review of the quality system for adherence to the requirements of Appendices A, B and C;

2) Review of staff qualifications and technical expertise necessary to produce acceptable proficiency testing samples;

3) Review of the sample manufacturing and verification procedures to ensure that the requirements of Appendices A and B are met;

4) Review of the procedures in place to ensure that all personnel are aware of and abide by standards of conduct for PT Providers and confidentiality of sample values; and

5) Review of data reporting systems to ensure that the requirements of Appendix C are met within the time periods specified in Chapter 2.

f) A ~~The~~ PTOB shall send a draft report to the PT Provider no later than ~~fourteen (14) calendar~~ 10 working days after the completion date of the inspection. A ~~The~~ PTOB shall allow the PT Provider ~~seven (7) calendar~~ five (5) working days to review and comment on the draft if the PT Provider finds any discrepancies and determines that revisions are necessary. A ~~The~~ PTOB shall then submit a final inspection report to the PT Provider no later than ~~thirty-five (35) calendar~~ 25 working days after the completion of the on-site inspection. The final report may only contain discrepancies and findings identified during the on site inspection or discussed during the exit briefing.

g) A ~~The~~ PTOB shall allow the Provider no less than ~~thirty (30) calendar~~ 20 working days to submit their response to the report. In order for the Provider's response to be considered acceptable, a ~~the~~ PTOB shall require that it include a description of corrective actions necessary to meet the criteria of Chapter 2, and Appendices A, B, and C.

D.2.3 Final Report Submittal NELAP and the PT Provider

No later than ~~ninety (90) calendar~~ 65 working days after the completion date of inspection, a ~~the~~ PTOB shall submit to NELAP and to the Provider a final report that includes the PTOB's final inspection report, the Provider's response to the inspection report, and the review of the initial application with associated documents. The report shall also include the PTOB's determination of whether the PT Provider is approved to provide NELAC samples. As part of the initial application process, the PT Provider will sign a waiver permitting the PTOB to release to NELAP non-confidential business information as necessary in the final report.

D.3.0 PTOB RESPONSIBILITIES REGARDING APPROVAL OF PT PROVIDERS

A ~~The~~ PTOB shall utilize the appropriate final report and associated documents submitted by the PT Provider to grant or deny approval to that Provider.

D.4.0 PTOB RESPONSIBILITIES FOR ONGOING OVERSIGHT OF PT PROVIDERS

A ~~The~~ PTOB shall conduct ongoing oversight of all approved PT Providers. The oversight shall include at a minimum:

a) the use of referee laboratories to verify the concentrations of analytes in randomly selected PT Provider samples;

b) the statistical monitoring of PT Provider's study data to detect occurrences which indicate samples of unacceptable quality, i.e., failure rates that exceed expected norms, analyte standard deviations that exceed expected intervals, and analyte mean recoveries which are significantly above or below historical trends. The ongoing monitoring criteria to be used by a ~~the~~ PTOB will be developed by NELAC.

c) biannual on-site inspections of the PT provider review and monitoring of critical operational parameters of the PT provider, i.e., change in senior management, sale of the company.

d) on-site inspections of the PT provider for cause.

Based upon the results of its ongoing oversight, the PTOB may determine that the Provider's approval status be reevaluated.

D.5.0 PTOB'S ANNUAL REPORT ON PROVIDER ACCREDITATION STATUS

A ~~The~~ PTOB shall submit an annual report to NELAP and all Accrediting Authorities ~~AA's~~ regarding the current accreditation status of PT Providers. NELAP may request additional information regarding a Provider including but not limited to: the PT Provider's monitoring data as described in Section D.4, final inspection reports and Provider responses, Initial Application Forms, the frequency and results of studies and complaints received regarding a Provider.

D.6.0 DEVELOPMENT AND MAINTENANCE OF A COMPREHENSIVE PT DATABASE

A comprehensive PT database will be developed and maintained by the PTOB(s) in conjunction with NELAC.

D.7.0 COMPLAINTS AND CORRECTIVE ACTION

A ~~The~~ PTOB shall evaluate all complaints that it receives regarding either approved or candidate PT Providers. If the PTOB determines that a complaint warrants investigation, the PTOB shall notify the Provider of the complaint. The PT Provider is required to resolve the complaint to the satisfaction of the PTOB within ~~thirty (30) calendar~~20 working days from the date the PTOB notifies the Provider. A ~~The~~ PTOB shall provide to the NELA~~P~~C Standing Committee on Proficiency Testing a summary of all PT Provider complaints received the previous year.

D.8.0 LIST OF APPROVED PT PROVIDERS

A ~~The~~ PTOB shall maintain a list of approved PT Providers. The list shall be maintained on a continuing basis on an electronic bulletin board or similar means and will be readily available to laboratories seeking NELAC accreditation, state accrediting authorities and other interested parties. PT Providers must agree to abide by the provisions of NELAC regarding the advertising and marketing use of the designation, "NELAP-designated PTOB Approved Proficiency Test Provider".

D.9.0 SPONSORSHIP OF ANNUAL *NELAC PROFICIENCY TESTING CAUCUS*

The PTOB(s) shall, in conjunction with NELAC, sponsor an annual *NELAC Proficiency Testing Caucus*. The *Caucus* shall, if possible, be held in conjunction with the annual NELAC meeting. The purpose of the *Caucus* is to provide a forum for PT Providers, Accrediting Authorities, laboratories, federal agencies, and other interested parties to exchange information regarding the PT study results of the previous year. The *Caucus* shall include technical presentations and open discussions on means to improve the Proficiency Testing aspect of NELAC with a continuing goal of improving the quality of environmental data generated by the NELAC accredited laboratories.

D.10.0 PTOB ETHICS

This section describes the overall ethics and standards of conduct that must be adhered to in order for a ~~the~~ PTOB to implement and administer a successful PT Provider oversight program. A ~~The~~ PTOB shall serve as an impartial body designed to objectively evaluate information about PT Providers and use this information to make sound determinations regarding Providers' approval status. A ~~The~~ PTOB shall be able to certify to any interested party that it is free of any organizational or financial conflict of interest, which would prevent it from complying with the requirements of Appendix D. A ~~The~~ PTOB shall remain unbiased in evaluating information gathered and received including inspection reports, referee sample results, complaints, and any other information obtained regarding a PT Provider. The PTOB shall evaluate all information gathered and received about a Provider related to providing NELAC PT samples, and determine which information is relevant to the approval status of a Provider, and provide that information to NELAP, the Accrediting Authorities ~~AAs~~, the laboratories, and the public as appropriate.

D.11.0 CONFIDENTIALITY

A portion of the information provided to a ~~the~~ PTOB by the PT Provider in the course of its inspection and oversight activities will be proprietary in nature. A ~~The~~ PTOB will agree to maintain the confidentiality of proprietary information provided to it by the PT provider.

APPENDIX E

MICROBIOLOGY

E.0.0 PURPOSE

This appendix outlines the requirements for microbiological proficiency testing under the Safe Drinking Water (SDWA) and Clean Water (CWA) Acts. Microbiological testing for other EPA Programs will be added as required. Semi-annual proficiency testing is required per the schedule contained in Section 2.4.

E.1.0 SAMPLES

E.1.1 SDWA Samples

Samples shall present themselves as either as full volume samples or preparations easily reconstituted to full volume samples. For the SDWA, there shall be ten 100+ ml. samples for the qualitative determination (Presence/Absence) of Total coliform and Fecal coliform (or *E coli*). Sample sets which are provided to the laboratories shall contain bacterial contaminates that produce the following:

- ~~Sheen colonies which will verify~~ Verification as total and fecal coliforms (e.coli).
- ~~Sheen colonies which will verify~~ Verification as total coliforms, but not as fecal coliforms.
- ~~Atypical colonies~~ Bacterial contaminates which will not verify as total or fecal coliforms.

Furthermore, each set will contain the following samples:

- ~~Three~~ One to four samples containing an aerogenic strain of Escherichia coli for total and fecal coliform positive results using all EPA approved methods.
- ~~Three~~ One to four samples containing Enterobacter sp. or other microorganisms ensuring a total coliform positive and fecal coliform negative result using all EPA approved methods.
- ~~Two~~ One to four samples containing Psueudomonas sp. or other microorganisms ensuring a total and fecal coliform negative result using all EPA approved methods.
- ~~Two~~ One to four blank samples.
- Optionally, one sample for the quantitative determination of Heterotrophic Plate Count.

Sample sets for qualitative analysis shall be randomly composed of samples that are Total coliform absent, Total coliform only present and Fecal coliform (E. coli) present.

E.1.2 CWA Samples

For the CWA, one sample shall be provided for the quantitative determination of Total coliform or Fecal coliform. Providers may require laboratories to analyze samples during a fixed time period after sample shipment or at any time during the testing period which shall not exceed the time limit set in Chapter 2.

E.2.0 SAMPLE PREPARATION AND QUALITY CONTROL

Proficiency test sample providers shall select bacterial strains and *holding media* that produce the appropriate biochemical reactions for *all* approved analytical methods. This shall be documented by analyses performed by the provider prior to sample shipment. The provider must also demonstrate that the samples are stable by analysis of a randomly selected set either after the study closing date or in the case of a study with a fixed testing period, on the last working day of the testing period.

E.3.0 SCORING

E.3.1 Qualitative Analyses, *SDWA Samples*

Participating laboratory results shall be considered Acceptable or Unacceptable when compared to the known presence or absence of Total coliform or Fecal coliform (or *E. coli*) bacteria. ~~For ten (10) samples, 20 results are to be reported.~~ Passing shall be considered as ~~18 Acceptable results~~ nine out of ten samples having acceptable results and no false negatives reported.

E.3.2 Quantitative Analyses

Quantitative result data sets shall be evaluated by analytical method using standard statistical analysis with outlier rejection. Most Probable Number data shall be transformed to logs prior to statistical analysis. Acceptable results are those that are within the 99% confidence limits as set by the mean, standard deviation and set size *(n)* for their respective data set.

E.3.2.1 Minimum Laboratory Participation

Each PT provider's microbiological data set shall be comprised of at least 20 valid data points for each method evaluated. Sample sets of less than 20 data points may be used only with the approval of the PTOB.

~~Quantitative result data sets shall be evaluated by analytical method using standard statistical analysis with outlier rejection. Most Probable Number data shall be transformed to logs prior to statistical analysis. Acceptable results are those that are within the 99% confidence limits as set by the mean, standard deviation and set size (*n*) for their respective data set.~~

APPENDIX F

RADIOCHEMISTRY

DRAFT

This appendix is currently being revised by the PT Committee and will not be presented for vote at NELAC IV.

Please submit any comments to the PT Committee Chair, Anne Rhyne.

F.0 PURPOSE

This appendix outlines variances from Chapter 2 deemed necessary or desired for radiochemical proficiency testing under NELAP. USEPA program requirements, for example for Safe Drinking Water Act compliance, will take precedence over the requirements set forth in this appendix.

F.1 Proficiency Test Samples

Samples for proficiency testing shall be consistent with, or easily converted to, common or required environmental sampling procedures so that standard sample preparation procedures, counting geometries, and other method requirements can be utilized as with the environmental samples normally analyzed.

F.2 Scoring and Reporting of Pt Results

F.2.1 Scoring

Scoring of proficiency testing results for radiochemical analyses should generally use fixed percentage limits of the true or reference value, such percentages representing the established capability of experienced laboratories performing the methodology as written. For established programs pre-existing adoption of this appendix and using statistical limits (e.g., 99% or 95% prediction intervals based on all laboratories or a designated subset), such limits may continue to be used.

F.2.2 Reporting

Results of PT rounds shall be reported back to the participating laboratories and relevant accrediting authorities within ~~60~~ 40 working days of the close of the testing period.

F.2.3 Number of Data Points Needed

If 20 data points are not available for a radiochemical proficiency testing study, evaluation of pooled data or other alternatives as approved by the Proficiency Testing Oversight Body may be used.

APPENDIX G

ENVIRONMENTAL TOXICOLOGY

DRAFT

This appendix is currently being revised by the PT Committee and will not be presented for vote at NELAC IV.

Please submit any comments to the PT Committee Chair, Anne Rhyne.

G.0 PURPOSE, SCOPE AND APPLICABILITY

This appendix defines the criteria applying the proficiency testing (PT) program to the following environmental toxicology programs: 1) whole effluent toxicity (WET), 2) sediment toxicity and 3) soils toxicity. The entire program has not been rewritten; instead, this appendix emphasizes deviations from the body of Chapter 2.

G.1 RATIONALE

Accreditation for environmental toxicology testing laboratories will be based on Proficiency Testing and on "onsite" audits, the latter including but not limited to an evaluation of personnel qualifications, facility acceptability, SOPs, QA/QC program, status of data/reports generated and routine standard toxicant testing. Proficiency Testing provides a snapshot of the laboratory's capability, however, due to the number of variables inherent to environmental toxicology testing it cannot carry the same weight as PT samples for chemical analytes. In order to make PT results more useful, the appendix will designate standard reference toxicant materials to be used by participating laboratories on a routine basis (i.e., monthly or by test organism batch, whichever is appropriate) for each field of testing, organism and protocol (method). PT samples will be comprised of unknown concentrations of these same reference toxicant materials making it easy to compare PT results to historical data and the laboratories' own standard reference toxicant cumulative summation charts. Every effort will be made by the oversight body working together with the providers to reduce the number of variables (i.e., organism age, etc.) while following the routine language of the EPA protocols.

G.2 FROM THE BODY OF CHAPTER 2 FOR COMMENTS

2.4 LABORATORY ENROLLMENT IN PROFICIENCY TESTING PROGRAMS

2.4.1 Required Level of Participation

Requirements as specified in Chapter 2.4.1, except that for environmental toxicology programs each laboratory shall participate in at least <u>one</u> PT study per year for each field of testing as designated (i.e., method and endpoint).

2.5 REQUIREMENTS FOR LABORATORY TESTING OF PT STUDY SAMPLES

- One PT study per year for each field of testing
- Analyze within ~~30~~ 20 working days of sample receipt; report results within ~~30~~20 working days of completion.
- Samples will be analyzed exactly the way the lab always runs these tests (this includes dilution water, number of replicates, water changes, etc.) - "real world testing".

2.7 PT CRITERIA FOR LABORATORY ACCREDITATION

2.7.2 Initial and Continuing Accreditation

As specified, except that for initial or continuing accreditation, completion dates of successive proficiency testing studies for a given field of testing must be at least annual (i.e., not more than 12 months apart) and at least ~~30~~ 20 working days apart (i.e., participation in a second round or remedial study may not occur within ~~30~~ 20 working days of the first or failed study). Failure to meet the annual schedule will be regarded as a failed study.

2.7.3 Supplemental Studies

As specified, except in line 2 of 2.7.3, change “semi-annual” to “annual.”

G.3 FIELDS OF TESTING

The environmental toxicology PT program will be organized by fields of testing based on method (including matrix, test organism, and exposure system) and endpoint(s). Laboratories may choose to participate in one or more PT fields of testing, or portions thereof.

G.3.1 Whole Effluent Toxicity (WET)

Test Organism	Test Conditions	Method Code[1]	Standard Toxicant
Pimephales promelas	48-h acute, non-renewal, 20 C, synthetic MHW[2]	11	NaCl
Pimephales promelas	7-d chronic, daily renewal, synthetic MHW	15	NaCl
Ceriodaphnia dubia	48-h acute, non-renewal, 20 C, synthetic MHW	17	NaCl
Ceriodaphnia dubia	7-d chronic, daily renewal, synthetic MHW	21	NaCl
Daphnia pulex	48-h acute, non-renewal, 20 C, synthetic MHW	32	NaCl
Mysidopsis bahia	48-h acute, non-renewal, 20 C, synthetic SW[3]	42	copper
Mysidopsis bahia	7-d chronic, daily renewal, synthetic SW	43	copper
Menidia beryllina	48-h acute, non-renewal, 20 C, synthetic SW	44	copper
Menidia beryllina	7-d chronic, daily renewal, synthetic SW	??	copper
Cyprinodon variegatus	48-h acute, non-renewal, 20 C, synthetic SW	46	copper
Cyprinodon variegatus	7-d chronic, daily renewal, synthetic SW	47	copper

[1] Method Code refers to '97 DMR-QA method summaries
[2] MHW = moderatley hard freshwater
[3] SW = sea water

G.3.2 Sediment Toxicity (Solid Phase)

- Amphipod - fresh & salt
- Mollusca - fresh & salt
- Polychaete - fresh & salt
- Standard reference toxicant type test - 96 hour ($CdCl_2$)
- References
  EPA/503/8-91/001
  EPA/823/B-94/002

G.3.3 Soil Toxicity

Test Organism	Test Conditions	Method Code	Standard Toxicant
Eisenia foetida survival test	14-d static, non-renewal, 20±2 C, 24L:0D	TBS[1]	TBS
Lettuce (Lactuca sativa) seed germination test	120-h static, non-renewal, 24±2 C, 16L:8D	TBS	TBS
Lettuce (Lactuca sativa) root elongation test	120-h static, non-renewal, 24±2 C, 0L:24D	TBS	TBS

[1] TBS = to be specified